K094036

JAN 25 2010

510(k) Summary

SUBMITTER INFORMATION

A. Company Name: Spectranetics Corporation, Inc.

B. Company Address: 9965 Federal Blvd
Colorado Springs, CO 80921

C. Company Phone: 719-447-2000/ 1-800-633-0960

D. Company Facsimile: 719-447-2040

DEVICE IDENTIFICATION

A. Device Trade Name: Spectranetics Turbo-Tandem™ System

B. Device Common Name: Percutaneous Laser Ablation Catheter

C. Classification: Catheter, Percutaneous

D. Device Class: Class II (per 21 CFR 870.1250)

E. Device Code: DQY

F. Establishment Registration Number: 3007284006 (Federal Facility) and 1721279 (Cascade Facility)

PERFORMANCE STANDARDS

Performance standards do not currently exist for these devices. None established under Section 514.

DEVICE DESCRIPTION

The Turbo-Tandem™ System (Laser Guide Catheter with Laser Ablation Catheter) is a laser atherectomy catheter constrained within a guiding catheter to facilitate the offset (biased position) of the laser ablation catheter. The Turbo-Tandem System is designed to be used to directionally ablate infrainguinal concentric and eccentric lesions in vessels 5mm or greater at or above the knee. The Turbo-Tandem System is not designed to be used in total or sub-total occlusions. In the event of a total or sub-total occlusion a pilot channel is recommended. The guiding catheter portion of the Turbo-Tandem™ System is used to offset the distal end of the incorporated laser catheter from the central plane of the vessel lumen allowing for circumferential guidance and positioning of the laser catheter within the vessel. The Turbo-Tandem™ System is 7F sheath compatible with a maximum crossing profile of 0.160" (4.0mm) with the laser catheter extended or offset position. The incorporated laser catheter is constructed of multiple optical fibers arranged circumferentially around a 0.014" (0.35mm) guidewire compatible lumen and has a fiber optic surface area similar to a 2.0mm laser catheter. The laser catheter is connected to the Spectranetics CVX-300® Excimer Laser System by means of an optical coupler and tail-tubing. The guiding catheter portion of the Turbo-Tandem™ System is comprised of a handle with an incorporated flush port, proximal coupler, tail tubing, strain relief tubing, braided shaft with a hydrophilic coating, two radiopaque marker bands in the distal tip with a platform, and one radiopaque marker band at the distal end of the laser catheter. Figure 1 describes the location of the Turbo-Tandem™ System components.

INDICATION FOR USE

Indicated for atherectomy of infrainguinal arteries.

SUBSTANTIALLY EQUIVALENT DEVICES

In Spectranetics' opinion, the Turbo-Tandem System is believed to be substantially equivalent to the following predicate device currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- Spectranetics first generation Turbo Tandem System - K091299

Labeling, packaging, and sterilization of the Spectranetics Turbo-Tandem System have not changed from the predicate device listed above. The IFU has been modified to reflect the new handle, hydrophilic coating and flush port modifications for the second generation Turbo-Tandem.

SUMMARY OF STUDIES

Spectranetics performed device integrity testing to support that the Turbo-Tandem System is equivalent to the predicate devices. All device integrity test results for the Spectranetics Turbo-Tandem System met specified requirements.

CONCLUSION (STATEMENT OF EQUIVALENCE)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the second generation Spectranetics Turbo-Tandem™ System through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 25 2010

Spectranctics Corporation
c/o Mr. Michael Handley
Chief Compliance Officer and Vice President, Global Regulatory Affairs
9965 Federal Drive
Colorado Springs, CO 80921

Re: K094036
Trade Name: 7FR Turbo-Tandem™ Catheter System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II (two)
Product Code: MCW, DQY
Dated: December 28, 2009
Received: December 30, 2009

Dear Mr. Handley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indication for Use

Premarket Notification Number: ~~TBD~~ K094036

Device Name: Turbo-Tandem™ System

Indication for Use

Turbo-Tandem™ System is indicated for atherectomy of infrainguinal arteries.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K094036

Prescription Use: √ OR Over the Counter Use: __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)